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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,345	03/25/2002	Jan Gerrit Garssen	5034US	8607

7590 09/13/2004

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,345	GARSSEN ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25March2002, 30April2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10-16,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-16,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/01, 2/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Preliminary Amendment, received 25 March 2002, is acknowledged. Claims 1-7, 10-16, 18, and 19 have been amended. Claims 8, 9, and17 have been canceled.

2. Applicants' Second Preliminary Amendment, received 30 April 2002, is acknowledged. Claim 14 has been amended.

3. Claims 1-7, 10-16, 18, and 19 are pending and under consideration.

Priority Statement

4. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Specification

5. The disclosure is objected to because of the following informalities:

Page 2, lines 10-11, there is a reference to a nonspecified internet location,

Page 7, line 30, "untreatred" should be "untreated",

Page 8, lines 27-28, it is unclear what is meant by the sentence "As a capture antibody the Fab fragment of mAb 3F4 was coated."

Page 19, line 25, it is unclear what is meant by "but t"

Page 33, line 32, the Safar reference is 4(10):1157-1165, not as indicated, 10:1157-1165.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites "The method according to claim 1, wherein said method further is for reducing the risk of scoring a false-negative test result." It is unclear how claim 2 further limits claim 1 from which it depends. The recitation "wherein said method further is for reducing the risk of scoring a false-negative test result" is merely an intended use and imposes no new criticality onto the method of claim 1.

9. Claims 1-7, 10-16, 18, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 10 recite that the at least one sample is "derived" from a mammal. It is unclear what is meant by such derivation. It is recommended that the claims recite for example, "obtained" or "isolated from". Claims 2-7, 11-16, 18, and 19 depend from claims 1 and 10, but do not clarify the indefiniteness.

Claims 1 and 10 recite treatment of at least one sample with quanidine thiocyanate "or a functional equivalent thereof". It is unclear what is meant by "a functional equivalent thereof"

as the specification does not define the phrase. Claims 2-7, 11-16, 18, and 19 depend from claims 1 and 10, but do not clarify the indefiniteness.

Claim 14 recites peptide sequences "or functional equivalents thereof". It is unclear what is meant by the phrase as the specification does not define the phrase.

Claim 18 recites a kit of "parts comprising means for performing" the method of claim 1. It is unclear what are the metes and bounds of what constitutes a "part comprising means of performing" the method.

Claim 19 recites the kit of claim 18 wherein said kit of parts is "designed" for mass-screening purposes. It is unclear what are the metes and bounds of what constitutes a "design" for mass-screening purposes.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-5, 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bell et al (*Neuropathology and Applied Neurobiology*, 23(1):26-35, 1997).

Claim 1 recites "A method for reducing the risk of scoring a false-positive test result in testing at least one sample derived from a mammal for the presence or absence of an aberrant prion protein, comprising treating said at lease one sample with quanidine thiocyanate or a functional equivalent thereof." The recitation of "for reducing the risk of scoring a false-positive test result in testing at least one sample derived from a mammal for the presence or absence of an aberrant prion protein" is intended use and does not place any patentably criticality on the

claimed method. The claimed method is "A method of treating at least one sample with guanidine thiocyanate or a functional equivalent thereof."

Claim 2 is the same method of claim 1, but with another intended use. This intended use does not place any patentably criticality on the claimed method.

Bell et al teach a method of treating at least one sample obtained from a mammal with quanidine thiocyanate and testing the sample in an immunoassay for mass screen purposes (Abstract; Table 1; Table 2; Table 4).

Claim 10 recites "The method according to claim 1, further comprising treating at least one first sample from a mammal with quanidine thiocyanate or a functional equivalent thereof; leaving at least one second sample derived from said mammal untreated with quanidine thiocyanate or a functional equivalent thereof; and comparing the test result of said at least first sample with said at least second sample." The recitation of "for reducing the risk of scoring a false-positive test result in testing at least one sample derived from a mammal for the presence or absence of an aberrant prion protein" is intended use and does not place any patentably criticality on the claimed method.

Bell et al teach a method of treating at least one sample obtained from a mammal with quanidine thiocyanate, comparing it to an untreated sample, and detecting using immunoassay with antibody (SP40) directed against a proteinase K resistant part of the aberrant prion protein (Abstract; Table 1; Table 2; Table 4).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al (*Neuropathology and Applied Neurobiology*, 23(1):26-35, 1997).

The claims are drawn to kits comprising the means for performing the method of claim 1.

See *supra* for discussion of Bell et al concerning methods and reagents. It would have been obvious at the time the invention was made to a person having ordinary skill in the art to prepackage the reagents and procedural methods taught by Bell et al into a convenient kit form in order to facilitate the assay of samples.

14. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al (*Neuropathology and Applied Neurobiology*, 23(1):26-35, 1997) in view of Schreuder et al (WO97/37227).

The claims are drawn to the method of claim 1 wherein said mammal is a ruminant and wherein said ruminant is ovine or bovine.

See *supra* for discussion of Bell et al concerning methods and reagents. Bell et al do not teach the immunoassays for ruminant samples.

Schreuder et al do teach methods for the detection of prion diseases in ovine and bovine species as well as man (section **Materials and Methods**). Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to expand the scope of the methods taught by Bell et al in order to facilitate testing of many different species of mammals which may be infected with prion disease.

15. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al (*Neuropathology and Applied Neurobiology*, 23(1):26-35, 1997) in view of Prusiner et al (U.S. Pat. No. 5565186).

The claims are drawn to the method of claim 11 wherein the detection is by dot blot enzyme-linked immunoassay.

See *supra* for discussion of Bell et al concerning methods and reagents. Bell et al do not teach the dot blot mmunoassays.

Prusiner et al do teach dot blot immunoassays for the detection of prions (Ex. 6, Immunoblot analysis). Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to expand the utilize dot blot immunoassays as taught by Prusiner et al with the sample preparation methods taught by Bell et al in order to facilitate simultaneous testing of many samples for prion disease.

Conclusion

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

September 8, 2004